REMARKS/ARGUMENTS

The Present Invention

The present invention is directed to isolated cancer peptides or functionally equivalent variants thereof, compositions thereof, and immunogens comprising the compositions.

The Pending Claims

Claims 3, 5-8, 10, 12-15, 26, 28, 29, 67-77, 83-85, and 87-103 are pending, of which claims 3, 5-8, 10, 12-15, 67-77, and 87-97 are directed to isolated cancer peptides and variants thereof, claims 26 and 98 are directed to compositions, and claims 28, 29, 83-85, and 99-103 are directed to immunogens. Claims 89-91 are indicated to be objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

The Amendments to the Claims

Claims 3 and 26 have been amended to recite "amino acids 53-62 of SEQ ID NO: 4" instead of "amino acids 55-62 of SEQ ID NO: 4." Also, claims 3 and 26 have been amended to delete the phrase "about 10 contiguous amino acids of SEQ ID NO: 4." The phrase "is immunologically recognized by antigen specific cytotoxic T lymphocytes" has been changed to "stimulates cancer antigen specific cytotoxic T lymphocytes" which is supported by the specification at, for instance, page 9, lines 23-26. The phrase "at least 85% sequence homology" has also been deleted. Claims 3 and 26 now recite "wherein the functionally equivalent variant has at least 90% sequence identity with amino acids 53-62 of SEQ ID NO: 4" which is implicitly supported by the specification at, for example, Table 7, which lists several examples of peptides that are at least 90% identical in sequence to amino acids 53-62 of SEQ ID NO: 4. Claims 3 and 26 have been further amended to recite lower case roman numerals within part (a) to make clear that the functionally equivalent variants being claimed are variants of amino acids 53-62 of SEQ ID NO: 4. No new matter has been added by way of these amendments.

Interview Summary

Applicants wish to thank Examiners Blanchard and Helms for the Examiner Interview held on June 23, 2005. The arguments presented on page 2 of the Advisory Action dated May 18, 2005, were discussed. Specifically, claims 3, 5, 26, and 87 were discussed with respect to the Section 112 rejections and amendments to claims 3 and 26 were proposed. Agreement was reached with respect to claim 87 having antecedent basis in claim 3. Also, it was agreed that the claim amendments proposed in the interview and shown herein obviate the new matter and indefiniteness rejections of the functionally equivalent variants of amino acids 53-62 and of claims 3, 5, 26, and 87, respectively. However, no agreement was reached with respect to the enablement rejection and with respect to the written description rejection as it pertains to homologous sequences of SEQ ID NO: 4.

Discussion of the Advisory Action

In the Advisory Action dated May 18, 2005, the Office contends that claim 3 introduces new matter, since the claim allegedly reads on any functional variant of a cancer peptide consisting of amino acids 127-136. However, the claim requires that the functionally equivalent variant "has at least 85% sequence identity with amino acids 53-62 of SEQ ID NO: 4." Thus, the claimed functionally equivalent variants are, in fact, functionally equivalent variants of the peptide consisting of amino acids 53-62, and not functionally equivalent variants of the peptide consisting of amino acids 127-136. Further, it should be noted that amino acids 53-62 (ASGPGGGAPR) are significantly different from amino acids 127-136 (TVSGNILTIR), such that a peptide having at least 85% sequence identity with amino acids 53-62 of SEQ ID NO: 4 would not be considered by one of ordinary skill in the art as a functional variant of amino acids 127-136. In this regard, functional variants of the peptide consisting of amino acids 127-136 are not within the scope of claim 3.

The Office contends that it is unclear whether the functional variant peptide consisting of amino acids 127-136 of SEQ ID NO: 4 has at least 85% sequence identity with amino acids 53-62 of SEQ ID NO: 4. As stated above, the claim does not encompass functional variants of the peptide consisting of amino acids 127-136 of SEQ ID NO: 4.

However, in order to advance prosecution and not in acquiescence of the rejection, claims 3 and 26 have been amended to make clear that the functionally equivalent variants are functionally equivalent variants of amino acids 53-62.

The Office alleges that claim 5 lacks antecedent basis for "cytotoxic T lymhphocytes." Claim 3, which is the claim on which claim 5 is dependent, in addition to claim 26, has been amended herein to recite the term "cytotoxic T lymphocytes." Thus, claim 5 has proper antecedent basis.

The Office alleges that "claim 87 still recites that the cancer peptide is 'about 10 amino acids in length.'" Presumably, the Office is contending that peptides of this length are not encompassed within the claim on which claim 87 depends, i.e., claim 3. However, claim 3, as amended herein, requires that the claimed peptides have a minimum length of 10 amino acids, as the claim requires that the peptide consists of amino acids 53-62 or amino acids 127-136. The peptide of claim 3 *optionally* consists of "1 to about 10 additional contiguous amino acids of SEQ ID NO: 4 at the N-terminus of the peptide." Thus, a peptide that is about 10 amino acids in length is within the scope of claim 3, and accordingly, claim 87 has antecedent basis in claim 3.

With respect to the written description rejection, the Office maintains that the claims still encompass homologous sequences of SEQ ID NO: 4 from other mammalian sources, and that the specific variant sequences disclosed in Tables 6 and 7 are allegedly insufficient to support the broader genus encompassed by the claims.

The term "homology" means "similarity in structure of an organ or a molecule, reflecting a common evolutionary origin" (Alberts et al., Molecular Biology of the Cell, 3rd ed.Garland Publishing, Inc., New York, 1994, page G-12). Further, "homologous proteins always contain a core region where the general folds of the polypeptide chains are very similar. This core region contains mainly the secondary structure elements that build up the interior of the protein: in other words, the scaffolds of homologous proteins have similar three-dimensional structures." (Branden and Tooze, Introduction to Protein Structure, Garland Publishing, Inc., New York, 1991, page 249).

The present invention is directed to isolated cancer peptides or functionally equivalent variants thereof, compositions thereof, and immunogens comprising the compositions. The isolated cancer peptides are at most about 20 amino acids in length. In this regard, the claims do not encompass homologous sequences of SEQ ID NO: 4, a 180-amino acid sequence, from other mammalian sources. Further, a peptide of at most about 20 amino acids cannot be considered a homologous protein of SEQ ID NO: 4, since its three-dimensional structure is not similar to that of SEQ ID NO: 4, or a homologous protein thereof.

The instant specification provides adequate written description of the claimed subject matter. As evidenced by the specification at, for instance, Tables 6 and 7, applicants were, in fact, in possession of the claimed peptides and variants thereof. At least 14 examples of the claimed peptides are presented therein. Thus, a representative number of species of the claimed genus is provided by the originally-filed specification. In view of the foregoing, the claimed peptides meet the written description requirement.

With respect to the new matter rejection, the Office contends that the scope of the claims extends beyond what is disclosed in the instant application as filed. Specifically, the Office maintains that the longest peptide disclosed in Table 7 is 15 amino acids in length, whereas the claims allegedly encompass peptides that are at least 17 or 19 amino acids in length. As stated above, claim 3 requires that the claimed peptide is at minimum 10 amino acids in length. The peptide can optionally consist of an additional 1 to about 10 contiguous amino acids. Thus, the peptide of claim 3 consists of between 10 and 20 amino acids. The originally filed specification supports such a range of peptide lengths. For example, SEQ ID NOs: 31, 14, 33, 30, 29, 28, 27, and 26, which are found in the specification at, for instance, Table 7, are 8, 9, 10, 11, 12, 13, 14, and 15 amino acids in length, respectively. SEQ ID NO: 45, which is disclosed in the originally-filed specification at, for example, page 11, line 10, is 20 amino acids. Further, the originally-filed application discloses that the peptides can be about 10 amino acids in length (bridging sentence beginning on page 8 and ending on page 9), and that the peptides can have about 1 to about 10 or about 1 to about 5 additional amino acids at the N-terminus (page 11, lines 3 and 4). Thus, the originally-filed application supports the claimed peptides of claim 3. Accordingly, the claimed subject matter is not new matter.

The Office questions which peptide in Table 6 or 7 is 85% identical with amino acids 53-62 of SEQ ID NO: 4. SEQ ID NOs: 34 – 44, for example, are at least 85% identical with amino acids 53-62, as they are 90% identical with amino acids 53-62 of SEQ ID NO: 4. Thus, claims 3 and 26 as amended herein recite "at least 90% sequence identity of amino acids 53-62 of SEQ ID NO: 4."

With respect to the enablement rejection, the Office contends that a substantial number of variant sequences is encompassed within the claims, but that the specification teaches only how to test which peptides fall within the scope of the claims. The Office

further contends that the there is not a reasonable expectation of success in view of the fact that only 19 of 41 peptides tested in Tables 6 and 7 stimulated CTL activity.

A reasonable expectation of success is not required to demonstrate enablement. This is one of the criteria for a prima facie case of obviousness.

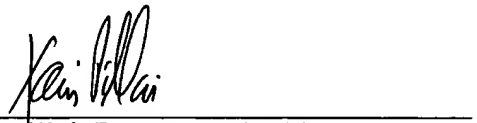
Further, as stated in the previous Response to Office Action, the level of one of ordinary skill, as evident by the prior art, is sufficient to make and use the full scope of the instant invention. The art of making and testing peptides for antigenicity was well-known long before the filing date of the instant application (see Gill et al. *J Biol Chem* 242: 3308-3318 (1967)). The art of testing peptides for the ability to stimulate antigen specific T lymphocytes was known at least as early as November 1994 (see Estaquier et al., *Eur J Immunol* 24(11):2789-95 (1994)).

The Office contends that Applicant has not provided a showing of good and sufficient reason why Gill et al. and Estaquier et al. were not presented earlier. Applicants hereby submit a Request for Continued Examination. The Office is respectfully requested to consider the teachings of these references and to reconsider the enablement rejection.

Conclusion

If, in the opinion of the Examiner, a telephone conference would expedite the prosecution of the subject application, the Examiner is invited to call the undersigned attorney.

Respectfully submitted,



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